

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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IN RE PRAECIS PHARMACEUTICALS, INC. : Civil Action
SECURITIES LITIGATION : No. 04-12581-GAO
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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
PRELIMINARY STATEMENT	1
ALLEGATIONS	6
ARGUMENT	6
I. ALL OF THE STATEMENTS IDENTIFIED IN THE COMPLAINT ARE NON-ACTIONABLE AS A MATTER OF LAW	6
A. General Statements Of Corporate Optimism Are Non-Actionable As A Matter Of Law	7
B. There Can Be No Liability For Statements Not Alleged To Be False Or Misleading	9
C. Statements Concerning Business Projections And Future Goals Are Forward-Looking And Protected By The PSLRA's Tripartite Safe Harbor Provisions	10
1. Forward-Looking Statements Accompanied By Meaningful Cautionary Language Are Protected By The PSLRA Safe Harbor Provisions	13
2. All Of The Forward-Looking Statements Are Non- Actionable Under The Independent "Known Falsity" Safe Harbor	17
II. THE SECTION 10(b) CLAIM FAILS FOR THE INDEPENDENT REASON THAT IT DOES NOT SATISFY THE RIGOROUS STANDARDS FOR PLEADING FRAUD AND SCIENTER	19
A. Dismissal Is Required Because The Complaint's Allegations Do Not State With Particularity Facts Supporting A Claim Of Securities Fraud	20
1. Plaintiffs' Allegations Are Insufficient To Demonstrate That The November 2003 Statements Were Knowingly False When Made ..	22
2. Plaintiffs Fail To Plead Particularized Facts Sufficient To Support Their Conclusory Assertions That The January 2004 Statements Were Fraudulent	24

3.	Plaintiffs Fail To Plead Particularized Facts Sufficient To Support Their Conclusory Assertions That The March And April 2004 Statements Were Fraudulent	26
4.	Plaintiffs Fail To Plead Particularized Facts Sufficient To Support Their Conclusory Assertions That The May Through October 2004 Statements Were Fraudulent	27
B.	Plaintiffs' Catch-All Allegations Of Scienter Are Conclusory And, Accordingly, Do Not Raise The Requisite Strong Inference Of Scienter	28
1.	Conclusory Allegations That Defendants Had Access To Unspecified Information Due To Their Positions Are Insufficient To Raise A Strong Inference Of Scienter	29
2.	Mere Allegations Of Stock Sales By A Single Defendant Fail To Raise A Strong Inference Of Scienter	30
III.	THE SECTION 10(b) CLAIM FAILS FOR THE ADDITIONAL REASON THAT PLAINTIFFS DO NOT ADEQUATELY PLEAD LOSS CAUSATION	31
IV.	PLAINTIFFS HAVE FAILED TO STATE A SECTION 20(a) CLAIM	34
	CONCLUSION	34

TABLE OF AUTHORITIES

<u>CASES</u>	<u>PAGE(S)</u>
<u>Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.</u> , 267 F.3d 30 (1st Cir. 2001)	1
<u>Arruda v. Sears, Roebuck & Co.</u> , 310 F.3d 13 (1st Cir. 2002)	6
<u>Baron v. Smith</u> , 380 F.3d 49 (1st Cir. 2004)	13
<u>Beddall v. State St. Bank & Trust Co.</u> , 137 F.3d 12 (1st Cir. 1998)	1
<u>Carney v. Cambridge Tech. Partners, Inc.</u> , 135 F. Supp. 2d 235 (D. Mass. 2001)	<i>passim</i>
<u>Clark v. TRO Learning Inc.</u> , Civ. A. No. 97-8683, 1998 WL 292382 (N.D. Ill. May 20, 1998)	17
<u>Dura Pharm., Inc. v. Broudo</u> , 125 S. Ct. 1627 (2005)	5, 31, 32
<u>Fitzer v. Sec. Dynamics Tech., Inc.</u> , 119 F. Supp. 2d 12 (D. Mass. 2000)	<i>passim</i>
<u>Greebel v. FTP Software, Inc.</u> , 194 F.3d 185 (1st Cir. 1999)	19, 31
<u>Harris v. Ivax Corp.</u> , 182 F.3d 799 (11th Cir. 1999)	13
<u>In re PLC Sys., Inc. Sec. Litig.</u> , 41 F. Supp. 2d 106 (D. Mass. 1999)	16
<u>In re Parametric Tech. Corp. Sec. Litig.</u> , 300 F. Supp. 2d 206 (D. Mass. 2001)	<i>passim</i>
<u>In re Peritus Software Servs., Inc. Sec. Litig.</u> , 52 F. Supp. 2d 211 (D. Mass. 1999)	8
<u>In re Segue Software, Inc. Sec. Litig.</u> , 106 F. Supp. 2d 161, 165 (D. Mass. 2000)	6
<u>In re Sofamor Danek Group, Inc.</u> , 123 F.3d 394 (6th Cir. 1997)	28
<u>In re Stone & Webster, Inc. Sec. Litig.</u> , 414 F.3d 187 (1st Cir. 2005)	28, 34

<u>In re Sun Healthcare Group, Inc. Sec. Litig.</u> , 181 F. Supp. 2d 1283, 1289 (D.N.M. 2002)	17
<u>Lentell v. Merrill Lynch & Co. Inc.</u> , 396 F.3d 161 (2d Cir. 2005)	31, 32
<u>Lirette v. Shiva Corp.</u> , 27 F. Supp. 2d 268 (D. Mass. 1998)	20
<u>Maldonado v. Dominguez</u> , 137 F.3d 1 (1st Cir. 1998)	29
<u>Meyer v. Biopure Corp.</u> , 221 F. Supp. 2d 195 (D. Mass. 2002)	13
<u>Orton v. Parametric Tech. Corp.</u> , 344 F. Supp. 2d 290 (D. Mass. 2004)	<i>passim</i>
<u>SEC v. First Jersey Sec., Inc.</u> , 101 F.3d 1450 (2d Cir. 1996)	34
<u>Shaw v. Digital Equip. Corp.</u> , 82 F.3d 1194 (1st Cir. 1996)	7
<u>U.S. ex. rel Karvelas v. Melrose-Wakefield Hosp.</u> , 360 F.3d 220 (1st Cir. 2004)	6
<u>Van Ormer v. Aspen Tech., Inc.</u> , 145 F. Supp. 2d 101 (D. Mass. 2000)	<i>passim</i>

STATUTES**PAGE(S)**

15 U.S.C. §§ 78a <u>et seq.</u>	1
15 U.S.C. § 78u-4(b)(2)	28
15 U.S.C. § 78u-4(b)(3)	19
15 U.S.C. § 78u-5(c)(1)	11, 12, 13
15 U.S.C. § 78u-5(c)(2)	14
15 U.S.C. § 78u-5(e)	1
15 U.S.C. § 78u-5(i)(1)	11

RULES**PAGE(S)**

Fed. R. Civ. P. 9(b)	<i>passim</i>
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PRELIMINARY STATEMENT¹

Plaintiffs' entire case against Praecis Pharmaceuticals Incorporated ("Praecis"), and Malcolm Gelter, Kevin McLaughlin, Edward English and William K. Heiden (the "Individual Defendants" and, together with Praecis, "Defendants"), is premised upon the illogical allegation that Defendants all knew that the Company's first marketable drug, Plenaxis® "was a 'failed drug' from the beginning" (Consolidated Amended Complaint ¶ 100 (the "Complaint") (cited as "Compl. ¶ ____")), but nevertheless conspired to go forward full throttle with the hiring and training of dozens of sales people to sell this new drug, educating doctors around the country about the drug, establishing an extensive safety program in consultation with the FDA, and spending millions of dollars attempting to market the drug that Defendants already knew would not succeed in the marketplace. According to the Complaint, all of these knowingly pointless efforts were pursued by Defendants who all the while also made knowingly false optimistic forecasts and revenue projections with the secret intent of misleading investors.

Not surprisingly, this preposterous story is not supported by particularized factual pleadings. Instead, plaintiffs have alleged nothing more than impermissible "fraud by hindsight"

¹ Copies of documents that are central to plaintiffs' claims but were not attached to the Complaint may be reviewed on this motion to dismiss without converting the motion into one for summary judgment. See 15 U.S.C. § 78u-5(e). See also Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001) ("When the complaint relies upon a document, whose authenticity is not challenged, such a document 'merges into the pleadings' and the court may properly consider it under a Rule 12(b)(6) motion to dismiss."); Beddall v. State St. Bank & Trust Co., 137 F.3d 12, 16-17 (1st Cir. 1998) ("When, as now, a complaint's factual allegations are expressly linked to -- and admittedly dependent upon -- a document . . . the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)."). Copies of such integral documents are included in the accompanying Appendix Of Public Records (cited as "App. Ex. ____").

in an attempt to tell a nefarious tale out of what is no more than the unfortunate story of an unsuccessful effort to sell a new product.

On November 25, 2003, Praecis received Food and Drug Administration ("FDA") approval to market its very first product, Plenaxis®, a drug for the palliative treatment of advanced prostate cancer. (Compl. ¶ 2) Through March 2004, Praecis focused on building its commercial infrastructure to support the launch of Plenaxis®, including the hiring and training of medical science liaisons, regional sales managers and field sales representatives. (App. Ex. 6 at 1.) Praecis first began shipping Plenaxis® to distributors in January 2004, and generated revenue from Plenaxis® sales of approximately \$400,000 during the first quarter of 2004. (*Id.* at 2.) Plenaxis® sales during the second quarter of 2004, however, did not increase as rapidly as initially forecasted. As a result, on May 24, 2004 -- only 4 months after Praecis first began shipping Plenaxis® to distributors and more than 6 months before the purported class period ends -- Praecis informed investors of the slower than forecasted sales and withdrew those forecasts. Tellingly, the Complaint neglects to point out that Praecis expressly withdrew its sales forecast for Plenaxis® just four months after the new drug was launched, and further announced that because "the uptake of [Plenaxis®] by prescribers . . . has been somewhat slower than forecasted . . . [Praecis] is not in a position at this time to confirm its previously issued sales range forecast for 2004." (App. Ex. 8 at 2.)

Beyond omitting plain public disclosures that directly contradict plaintiffs' allegations of a conspiracy to market a drug that all Defendants "knew" would not sell and to conceal weak Plenaxis'® sales, the Complaint -- presumably in an attempt at particularity -- recites a plethora of business management decisions with which plaintiffs and their anonymous

"confidential sources" (almost all of whom are former sales representatives) vehemently disagree. Some of these allegations may be particular, but none of them are even logically consistent with plaintiffs' theme that Plenaxis® "was a 'failed drug' from the beginning," nor do they support a claim for securities fraud.

Instead, plaintiffs' allegations paint a picture of a small public company struggling to generate sales of a new product and experiencing difficulty in doing so:

- allegations of a "significantly flawed" pricing structure (id. ¶¶ 53-56);
- allegations that management threatened to fire sales representatives if sales did not improve (id. ¶¶ 71, 92);
- allegations that sales representatives were "intimidated" or had "low morale" (id. ¶¶ 72-74, 91).

Even if accepted as true, these are allegations of mismanagement; they do not state a claim for fraud under the federal securities laws. Indeed, the allegations suggest just the opposite: that Praecis was generally disappointed with sales of Plenaxis® and took a number of steps to try and boost sales (including terminating some salespeople and hiring new ones).

To be sure, hindsight certainly shows that Praecis was considerably less successful with Plenaxis® than it had expected and initially forecast. On December 6, 2004, Praecis announced that, because of a longer than expected sales cycle and physician concern over the uncertainty of reimbursement as a result of Medicare reform, it expected Plenaxis® sales to decrease from the third to fourth quarter of 2004. (Id. ¶ 134.) On May 20, 2005, Praecis further announced that it was discontinuing sales of Plenaxis® to new patients in the United States, and reducing its workforce by approximately 60%. (Id. ¶ 10.)

* * *

The fundamental logical problems of plaintiffs' Complaint lead to several independently dispositive grounds for dismissal as a matter of law.

First, the Complaint should be dismissed because of the 18 statements plaintiffs allege were fraudulent, not one of those statements is actionable as "fraud."² At least 7 of those statements were positive estimates of future sales and expressions of pride and confidence in the anticipated strength of Praecis' future business prospects. Such optimistic and vague statements concerning overall corporate health are immaterial as a matter of law because reasonable investors would regard them as nothing more than optimistic corporate "puffery." An additional 6 statements identified in the Complaint are forward-looking, and qualify for dispositive protection under at least one of the three separate, independently sufficient Private Securities Litigation Reform Act of 1995 ("PSLRA") safe harbor provisions. In this regard, Praecis' risk disclosures and cautionary language bar plaintiffs' fraud claims. Finally, there are 5 other statements challenged in the Complaint which plaintiffs allege were fraudulent without identifying in any manner what -- if anything -- is false or misleading about those statements.

Second, the Complaint should be dismissed for the independent reason that it fails to allege securities fraud with the requisite particularity. Although required to do so, the Complaint never specifies with particularity all facts supporting what Defendants purportedly knew and why Defendants' statements were false when made. Plaintiffs' "information and belief" criticisms are entirely based upon allegations provided by anonymous former employees. Yet, those anonymous former employees do not provide a single contemporaneous fact that supports

² The statements identified in the Complaint as materially false or misleading when made are contained in the Complaint at ¶¶ 105, 106, 107, 108, 109, 112, 113, 114, 118, 119, 120, 121, 124, 126, 127, 128, 131 and 132. (See also Exhibit A attached hereto.)

an inference that Defendants had knowledge of (or participated in) any fraudulent conduct. Instead, the anonymous former employees provide allegations that Praecis' unspecified "management" (i) engaged in "management by intimidation," (ii) "attack[ed] the qualifications of the sales representatives [and] threaten[ed] to fire the sales representatives," and (iii) exhibited a "lack of professionalism," and created a "'Jeckle [sic] and Hyde' work environment." (Compl. ¶¶ 71, 73, 91.) Controlling case law makes plain that allegations of mismanagement are insufficient to state a claim for fraud.

Moreover, the Complaint's allegations nowhere provide a strong inference of fraudulent intent. To the contrary, the only inference that can be drawn from the Complaint is that Praecis (a small biotechnology company marketing its first commercially approved product) found it to be more difficult to sell in the highly competitive marketplace than expected, and when it so learned, promptly informed investors of those difficulties.

Third, the Complaint should be dismissed for the further independent reason that plaintiffs have not alleged loss causation in a manner consistent with the Supreme Court's recent holding in Dura Pharm., Inc. v. Broudo, 125 S. Ct. 1627, 1631 (2005). Indeed, plaintiffs do not even attempt to allege facts that provide the requisite causal link between Defendants' alleged fraud and plaintiffs' purported losses. Nor could they; the very risks that materialized and precluded Praecis from meeting its sales forecasts were previously disclosed to investors and, accordingly, are not (and cannot be) fraudulent.

Finally, the Section 20(a) claim also should be dismissed because (i) there is no actionable predicate Exchange Act claim stated in the Complaint and (ii) plaintiffs have not even attempted to allege any culpable participation by any of the Individual Defendants to demonstrate

their contemporaneous knowledge or participation in any purported violation of the securities laws.

ALLEGATIONS³

The Complaint purports to identify 18 of Defendants' statements from November 2003 through October 2004 that plaintiffs allege were materially false and misleading when made. (*Id.* ¶¶ 105-109, 112-114, 118-121, 124, 126-128, 131-132.) Plaintiffs allege in conclusory fashion that every one of those statements were materially false and misleading because Defendants knew, or recklessly disregarded, that Plenaxis® "was a 'failed drug' from the beginning," before it was even sold. (*Id.* ¶ 100.) But, as a matter of law, none of those statements are even actionable.⁴ The chart attached hereto as Exhibit A identifies paragraph by paragraph each of the 18 statements challenged in the Complaint and summarizes why each statement is non-actionable.

ARGUMENT

I. ALL OF THE STATEMENTS IDENTIFIED IN THE COMPLAINT ARE NON-ACTIONABLE AS A MATTER OF LAW

All 18 of the statements plaintiffs allege to be false or misleading are non-actionable because they are either (i) immaterial as a matter of law or (ii) forward-looking, and

³ Although plaintiffs' well-pleaded allegations are taken as true solely for purposes of this Rule 12(b)(6) motion, the bald assertions, unsubstantiated conclusions and unsupported characterizations set forth in the Complaint are to be disregarded. *See, e.g., U.S. ex. rel Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 224 (1st Cir. 2004) (affirming dismissal); *Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 18 (1st Cir. 2002) (affirming dismissal); *In re Segue Software, Inc. Sec. Litig.*, 106 F. Supp. 2d 161, 165 (D. Mass. 2000) (dismissing complaint).

⁴ While the Complaint purports to assert liability against defendant Heiden for all statements during the purported class period, defendant Heiden resigned on September 7, 2004. (Compl. ¶ 23.) Accordingly, defendant Heiden cannot be liable for the statements identified in paragraphs 131 and 132 of the Complaint, which occurred in October 2004.

qualify for dispositive protection by at least one of the PSLRA's three safe harbor provisions or (iii) the Complaint does not allege that those statements are false or misleading. At a minimum, 7 statements are immaterial as a matter of law (see Compl. ¶¶ 106, 107, 112, 113, 118, 121 and 132), 5 additional statements are not even alleged to be false or misleading (see id. ¶¶ 105, 119, 124, 126 and 128) and the remaining 6 statements are protected forward-looking statements (see id. ¶¶ 108, 109, 114, 120, 127 and 131).⁵ Because the Compliant fails to identify even a single actionable statement, it fails as a matter of law and ought to be dismissed in its entirety.

A. General Statements Of Corporate Optimism Are Non-Actionable As A Matter Of Law

To state a viable claim of securities fraud, a plaintiff must allege, among other things, that the defendant made a materially false or misleading statement. Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 (1st Cir. 1996). A statement is material only if "a reasonable investor would have viewed it as having significantly altered the total mix of information made available." Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 298 (D. Mass. 2004) (quotation omitted). "[L]oosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker" are non-actionable corporate puffery. Shaw, 82 F.3d at 1217.

At least seven statements challenged by plaintiffs are nothing more than vague, optimistic statements of corporate health and, consequently, are immaterial as a matter of law:

- Plenaxis® approval "marks an important milestone in our transition to a fully integrated pharmaceutical company . . . [and] will bring a valuable therapy to those patients in the indicated population" (Compl. ¶ 106) (11/25/03, App. Ex. 1 at 1).

⁵ Seven of the 18 statements fall into more than one category, and therefore are non-actionable for multiple reasons. (See Compl. ¶¶ 106, 107, 112, 118, 120, 121, 131.)

- "We are extremely excited about the launch of our first product and the revenue opportunity it represents." (Compl. ¶ 107) (11/25/03, App. Ex. 1 at 3).
- "This approval marks our transition to a fully integrated pharmaceutical company with capabilities spanning drug discovery, clinical development, manufacturing and commercialization. . . . We believe that the approval of Plenaxis® confirms our team's ability to translate innovative scientific discoveries into commercial reality, effectively and efficiently." (Compl. ¶ 112) (1/30/04, App. Ex. 4 at 2).
- "The approval of Plenaxis™ is enabling us to build a commercialization infrastructure that adds tremendous value to our organization." (Compl. ¶ 113) (1/30/04; App. Ex. 4 at 4).
- "We are especially pleased to receive this news now, as initial interest in Plenaxis™ has been very encouraging" (Compl. ¶ 118) (3/31/04, App. Ex. 5 at 2).
- "Praecis continued to capitalize on the Plenaxis™ commercial opportunity. Although it is early in the Plenaxis™ launch, we are encouraged by the feedback from physicians" (Compl. ¶ 121) (4/30/04, App. Ex. 6 at 3).
- "We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis®, physicians are pleased with the results and thus are continuing to treat existing patients with, and identify new patients for, Plenaxis® therapy." (Compl. ¶ 132) (10/29/04, App. Ex. 11 at 3).

Courts in this Circuit routinely find substantially similar statements regarding the health of a company or the demand for its products non-actionable corporate puffery. See, e.g., Orton, 344 F. Supp. 2d at 300-01 (holding that statement "we are pleased with the performance" was non-actionable subjective opinion, and statement that the company was "position[ed] for long-term growth" is a "classic example of non-actionable corporate puffery"); see also In re Peritus Software Servs., Inc. Sec. Litig., 52 F. Supp. 2d 211, 219-20 (D. Mass. 1999) (holding as non-actionable corporate puffery statements that the company was experiencing "unprecedented

market demand for [its] products" and "[w]e are extremely proud of our success and our focus on near and long term opportunities").

B. There Can Be No Liability For Statements Not Alleged To Be False Or Misleading

A complaint alleging securities fraud must, among other things, (i) "specify each statement alleged to have been misleading" and (ii) "[specify] the reason or reasons why the statement is misleading." In re Parametric Tech. Corp. Sec. Litig., 300 F. Supp. 2d 206, 212 (D. Mass. 2001) (quotation omitted). Ten statements (or portions of those statements) identified in the Complaint are not even alleged to have been false or misleading and, therefore, cannot form the basis for a claim of securities fraud. (See Compl. ¶¶ 105, 107, 112, 118-120, 124, 126, 128, 131.)

Plaintiffs identify five public statements that report historical financial results, but do not allege that those historical results are in any way inaccurate.⁶ (Id. ¶¶ 112, 119, 126, 128, 131.) Paragraph 126 reports only historical financial results, and there are no allegations that those results are false. Paragraphs 112 and 131 report, in part, historical financial results and, again, those portions are unchallenged. Paragraphs 119 and 128 merely refer to Form 10-Qs filed on May 10, 2004 and August 9, 2004, respectively, and allege that those public filings "reaffirmed Praecis' previously announced financial results." (Id. ¶¶ 119, 128.)

The public statements discussing the PLUS Program also are unchallenged. (See id. ¶¶ 105, 107.) Indeed, paragraph 105 seems to be included for background and, in any event, plaintiffs do not allege that Defendants' descriptions of the PLUS Program are false or mislead-

⁶ See Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 250-51 (D. Mass. 2001) (dismissing complaint and holding that "accurate reporting of historical information cannot be the basis for a securities fraud claim").

ing. The same is true concerning the portion of paragraph 107 referencing the PLUS Program. Plaintiffs do not allege that the description of the PLUS Program or the statement that "[t]he PLUS Program highlights that patient safety is our number one priority . . ." are false or misleading. (*Id.* ¶ 107.)

Similarly, plaintiffs do not (and could not) challenge the historical information contained in the statements identified in paragraphs 118, 120 and 124 of the Complaint. Plaintiffs do not allege that the Plenaxis® historical summary discussed in paragraph 124 is false. Also unchallenged are the statements that Praecis "identified approximately 3,500 target prescribers" and "as of [May 24, 2004] over 2,200 physicians (and hospital pharmacies) have enrolled as authorized prescribes in the PLUS Program." (*Id.* ¶ 124.) Indeed, from the allegations in the Complaint, it is impossible to discern what, if anything, plaintiffs allege is false and misleading about paragraph 124.⁷

**C. Statements Concerning Business Projections
And Future Goals Are Forward-Looking And
Protected By The PSLRA's Tripartite Safe Harbor Provisions**

Under the multiple "safe harbor" provisions of the PSLRA, a forward-looking statement, whether written or oral, is non-actionable if (i) it is identified as forward-looking and is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or (ii) it is "immaterial" or (iii) plaintiff does not plead that the statement was made "with actual

⁷ Similarly undisputed are the emphasized portions of paragraphs 118 and 120 that report PLUS Program enrollment and historical sales of Plenaxis®: ". . . over 1,000 physicians and hospital pharmacies hav[e] enrolled in our PLUS[] Program [as of March 31, 2004]" (*id.* ¶ 118), and Praecis "generated net revenue of approximately \$0.4 million through sales to distributors . . ." (*id.* ¶ 120). Plaintiffs do not (and could not) challenge the factual accuracy of those statements.

knowledge . . . that the statement was false or misleading." See 15 U.S.C. § 78u-5(c)(1)(A)-(B).

The PSLRA defines forward-looking statements to include (i) projections of revenue, income, or earnings, (ii) management's plans and objectives, (iii) statements of future economic performance and (iv) statements concerning the assumptions underlying the foregoing. 15 U.S.C. § 78u-5(i)(1). Defendants' statements of revenue and market projections (see Compl. ¶¶ 108, 109, 114, 120), as well as statements of goals and plans for the future (see *id.* ¶¶ 106, 107, 121, 127, 131) plainly fall within that definition:

- Plenaxis® approval "will bring a valuable therapy to those patients in the indicated population who have limited or no other treatment options available" (Compl. ¶ 106) (11/25/03, App. Ex. 1 at 1) (emphasis added);
- "In addition, we plan to begin working with the FDA to explore other patient populations which could be appropriately treated with Plenaxis(TM) in the future," and "[w]e are extremely excited about the launch of our first product and the revenue opportunity it represents" (Compl. ¶ 107) (11/25/03, App. Ex. 1 at 3) (emphasis added);
- "As we said previously given our market share penetration and also our premium pricing assumptions, we've talked about a 15% plus revenue opportunity of the current \$1.2 billion market and none of that has changed" (Compl. ¶ 108) (11/26/03, App. Ex. 2 at 7) (emphasis added);
- "the current market for hormonal therapy is actually \$1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug" (Compl. ¶ 109) (11/26/03, App. Ex. 3 at 2) (emphasis added);
- "During 2004, the Company forecasts sales of Plenaxis(TM) to range from \$10.0 million to \$20.0 million and anticipates the ramp-up of revenues to be heavily weighted toward the second half of the year. . . . With respect to the future prospects for Plenaxis(TM), the market for currently available hormonal therapies to treat prostate cancer is approximately \$1.2 billion in the United States. The Company believes that the long-term revenue opportunity for Plenaxis(TM) may

represent 15% or more of this market." (Compl. ¶ 114) (1/30/04, App. Ex. 4 at 5) (emphasis added);

- "The Company generated net revenue of approximately \$0.4 million through sales to distributors, representing primarily initial stocking levels. Based upon the first quarter activity, the Company's prior Plenaxis(TM) sales forecast of \$10.0 million to \$20.0 million in revenue for 2004 remains unchanged." (Compl. ¶ 120) (4/30/04, App. Ex. 6 at 2) (emphasis added);
- "Although it is early in the Plenaxis(TM) launch, we are encouraged by the feedback from physicians and expect to build sales during the second half of the year as awareness of the product grows among urologists and oncologists." (Compl. ¶ 121) (4/30/04, App. Ex. 6 at 3) (emphasis added);
- "We expect to see Plenaxis(R) sales continue to build quarter on quarter over the course of the year. Longer-term, the Company continues to believe that the revenue opportunity for Plenaxis(R) may represent 15% or more of the \$1.2 billion hormone therapy market for prostate cancer in the United States. (Compl. ¶ 127) (7/30/04, App. Ex. 9 at 2-3) (emphasis added);
- As we look forward, we expect to begin new clinical trials related to our PPI-2458 and Apan clinical development programs. We further expect that our Direct Select(TM) technology platform will continue to expand in its scope and value as we look to partner this unique discovery capability. All of these changes should positively impact our future as a fully integrated biopharmaceutical organization and we are looking forward to a productive fourth quarter and 2005. (Compl. ¶ 131) (10/29/04, App. Ex. 11 at 2) (emphasis added).

The first safe harbor (see 15 U.S.C. § 78u-5(c)(1)(A)(i)) provides protection for all but one of the nine forward-looking statements identified in the Complaint because those statements were identified as forward-looking and accompanied by meaningful cautionary language.⁸ In addition, all of the forward-looking statements are protected by the third, and

⁸ The forward-looking statement in ¶ 109 -- which is a quotation from a CNBC television show interview -- was the only forward-looking statement not identified as such, and not accompanied by express cautionary language. (See App. Ex. 3.) That forward-looking statement is nevertheless protected by the third safe harbor of the PSLRA because plaintiffs have not sufficiently alleged actual knowledge of falsity at the time that statement was made in November 2003. Plaintiffs' failure to allege actual knowledge also renders this statement non-actionable for noncompliance with the particularity requirements of Fed. R. Civ. P. 9(b). (See *infra* Part II.A.)

independent, safe harbor (see id. § 78u-5(c)(1)(B)(i)) because plaintiffs have failed to allege with sufficient particularity that any Defendant knew a statement was false when made.⁹

**1. Forward-Looking Statements Accompanied
By Meaningful Cautionary Language Are
Protected By The PSLRA Safe Harbor Provisions**

The first safe harbor provides dispositive protection for 8 of the 9 oral and written forward-looking statements identified in the Complaint. (See Compl. ¶¶ 106-108, 114, 120-121, 127, 131.) Once the Court determines that the statements challenged in Praecis' press releases and conference call transcripts were identified as forward-looking and contained meaningful cautionary language, the inquiry as to those statements ends because they are consequently non-actionable as a matter of law. See Baron v. Smith, 380 F.3d 49, 53-54 (1st Cir. 2004) (affirming dismissal and holding that forward-looking statements in press release were protected by statutory safe harbor); Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 204 (D. Mass. 2002) (dismissing complaint on the grounds that identified statements were forward-looking and cautionary language "identifie[d] the risks at issue in the complaint"). In addition, if a forward-looking statement is "accompanied by 'meaningful cautionary language,' the defendants' state of mind is irrelevant." Harris v. Ivax Corp., 182 F.3d 799, 803 (11th Cir. 1999) (affirming dismissal on the grounds that forward-looking statements were protected by the PSLRA's safe harbor provisions) (emphasis added).

Every one of the press releases identified in the Complaint contained express warnings that forward-looking statements identified therein were subject to change and other

⁹ The forward-looking statements identified in ¶¶ 106, 107 and 121 are also protected by the second prong of the PSLRA safe harbor provisions because they are immaterial. (See supra Part I.A.)

certain risk factors,¹⁰ and included specific additional disclosures concerning where investors could obtain further information concerning the risk factors that might impact its future prospects:

This news release contains forward-looking statements, including, but not limited to, statements regarding the Company's commercialization of Plenaxis™ These statements are based on the Company's current beliefs and expectations as to future outcomes. Such statements are subject to numerous factors and uncertainties. These include, but are not limited to, the Company's ability to hire a sales force and successfully commercialize Plenaxis™, the Company's ability to manufacture Plenaxis™ on a commercial scale . . . as well as the risks set forth from time to time in the Company's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003. (11/25/03, App. Ex. 1 at 7) (emphasis added)¹¹

Praecis' SEC filings (which are specifically referenced in each of the press releases) also fully disclosed the risks associated with Praecis' business. Indeed, those public filings expressly warned investors of uncertainties and associated "Risk Factors:"

¹⁰ The statement challenged in ¶ 108 occurred during a conference call with investors and began with a cautionary statement that referred listeners to risk factors described in Praecis' SEC filings. (App. Ex. 2 at 1.) The safe harbor provisions of the PSLRA specifically provide that an oral forward-looking statement satisfies the first prong of the safe harbor when it is accompanied by an oral statement identifying readily available documents containing additional information concerning factors that could cause actual results to differ. 15 U.S.C. § 78u-5(c)(2). See also Parametric Tech., 300 F. Supp. at 219 (dismissing complaint and finding similar cautionary language sufficient to invoke safe harbor protection).

¹¹ The press releases dated January 30, 2004, April 30, 2004, July 30, 2004 and October 29, 2004 contain substantially similar language, tailored for the specific content of the release. (See App. Exs. 4, 6, 9 and 11.)

Form 10-Q For The Period Ending September 30, 2003

Even if we receive approval for the marketing and sale of Plenaxis or any of our other product candidates, they may fail to achieve market acceptance and, accordingly, may never be commercially successful.

Many factors may affect the market acceptance and commercial success of Plenaxis or any of our other potential products, including:

- the scope of the patient population and the indications for which Plenaxis . . . [is] approved;
- the terms of any risk management and/or controlled or managed distribution program required by the FDA in connection with the approval of Plenaxis;
- the product labeling or the product insert required by the FDA for Plenaxis;
- the effectiveness of Plenaxis . . . including any potential side effects, as compared to alternative treatment methods;
- the extent and success of our marketing and sales efforts relating to the marketing and sale of Plenaxis;
- the rate at which Plenaxis . . . [is] reimbursed by third-party payors, in particular Medicare;
- the competitive features of our products as compared to other products, including the frequency of administration of Plenaxis as compared to other products, and doctor and patient acceptance of these features;
- the cost-effectiveness of Plenaxis . . . and the availability of insurance or other third-party reimbursement, in particular Medicare;
- the timing of market entry as compared to competitive products; and
- unfavorable publicity concerning Plenaxis. (App. Ex. 12 at 16)

Form 10-K For The Period Ending December 31, 2003

Our business is dependent on the commercial success of Plenaxis. If Plenaxis fails to achieve market acceptance, it may never be commercially successful and we may be unable to continue our operations as planned.

The success of our business is dependent on the successful commercialization of Plenaxis. . . . Many factors may affect its market acceptance and commercial success of Plenaxis, including:

- the scope of the patient population and the indications for which Plenaxis was approved;
- the terms of the risk management required by the FDA in connection with the approval of Plenaxis;
- the product labeling and the product insert required by the FDA;
- the effectiveness of Plenaxis and the potential side effects . . . as compared to alternative treatment methods;
- the extent and success of our marketing and sales efforts;
- the cost-effectiveness of Plenaxis and the availability of insurance or other third-party reimbursement, in particular Medicare, for patients, and the rate of such reimbursement;
- the competitive features of Plenaxis as compared to other products or treatment options, including the frequency of administration of Plenaxis as compared to other products, and doctor and patient acceptance of these features; and
- unfavorable publicity concerning Plenaxis. (App. Ex. 13 at 31-32.)¹²

The foregoing specifically identified risk factors concerning Plenaxis® future prospects render Defendants' forward-looking statements protected by the safe harbor. See In re PLC Sys., Inc. Sec. Litig., 41 F. Supp. 2d 106, 113, 118 (D. Mass. 1999) (holding that press release which cross-referenced "risk factors listed from time to time in the Company's SEC reports" brought the press releases within the safe harbor provision). The PSLRA accords those statements dispositive protection against any claim of "fraud." See Parametric Tech., 300 F. Supp. 2d at 218-19 (finding forward-looking statements concerning revenue projections protected by the PSLRA's safe harbor provisions); Carney, 135 F. Supp. 2d at 251 (holding statements non-actionable where press release contained "a full paragraph entitled 'Forward

¹² The Form 10-Qs for the periods ending March 31, 2004 and June 30, 2004 contain substantially similar language and Risk Factors. (See App. Ex. 7 at 16-17; App. Ex. 10 at 19.) Moreover, those Form 10-Qs contained more detailed cautionary language concerning, for example, physician education regarding Plenaxis®. (See, e.g., App. Ex. 10 at 20 ("physicians may not prescribe Plenaxis® if we fail to provide adequate education about its benefits and uses").)

Looking Statements,' which specifically warn[ed] potential investors that the company's projections [were] subject to risks and uncertainties") (quotation omitted).

2. All Of The Forward-Looking Statements Are Non-Actionable Under The Independent "Known Falsity" Safe Harbor

Separate and apart from the first two safe harbors, the PSLRA establishes a third, independent (and equally dispositive) safe harbor that precludes liability for any forward-looking statement -- even if not identified as such -- unless the maker of the statement had "actual knowledge it was false or misleading." Carney, 135 F. Supp. 2d at 245 (citation omitted).

All of the forward-looking statements are non-actionable because plaintiffs have not alleged facts giving rise to a strong inference that Defendants had actual knowledge of their falsity. See Parametric Tech., 300 F. Supp. 2d at 219 (holding that forward-looking statements are protected by the PSLRA's safe harbor provisions "'unless the maker of the statement had actual knowledge it was false or misleading'") (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 201 (1st Cir. 1999)); see also In re Sun Healthcare Group, Inc. Sec. Litig., 181 F. Supp. 2d 1283, 1289 (D.N.M. 2002) (dismissing complaint on grounds that challenged statements were non-actionable forward-looking statements and stating that "[a]ctual knowledge is a higher level of scienter than the 'recklessness' required by the pleading standards of the [PSLRA]").¹³

¹³ Actual knowledge is not adequately alleged when the complaint pleads that "defendants knew or were reckless in failing to know" of the alleged fraudulent conduct. Clark v. TRO Learning Inc., Civ. A. No. 97-8683, 1998 WL 292382, at *5 (N.D. Ill. May 20, 1998) ("By this alternative allegation [plaintiff] raised the possibility that defendants were merely reckless in their statements and that they lacked the required knowledge to state a claim. This alone is fatal . . ."). The Complaint in this case invokes the same pleading defect. (See, e.g., Compl. ¶ 151 ("defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth . . .")).

In order to overcome this alternative safe harbor, the Complaint must make allegations of each Defendants' actual knowledge at the time the forward-looking statements were made. In addition, the Complaint must allege that each such statement was false or misleading when made. The Complaint falls far short of adequately pleading these prerequisites.

The "known falsity" safe harbor precludes liability for plaintiffs' allegations of "knowledge," which are nothing more than conclusory allegations -- made with the benefit of hindsight -- that Defendants *must have known* that the forward-looking statements were false when made because (as it later came to pass) Plenaxis® ultimately did not sell well. Indeed, plaintiffs conclusorily assert that Defendants "knew" that Plenaxis® "was a 'failed drug' from the beginning" because (i) Plenaxis® would not be profitable to physicians, (ii) the "black box" warning label would make it difficult to sell Plenaxis® and (iii) competition from another drug would inhibit sales. (Compl. ¶¶ 47-59). But those "fraud by hindsight" allegations are insufficient to ascribe actual knowledge of falsity to each Defendant at the time each statement was made. Accordingly, all of the forward-looking statements are protected by the PSLRA's "known falsity" safe harbor provision, and are non-actionable as a matter of law.¹⁴ See Parametric Tech., 300 F. Supp. 2d at 219 (claims dismissed on "known falsity" safe harbor grounds because "[t]he facts pleaded about what [defendant] or other insiders knew are too general to permit an inference -- even a merely reasonable one -- that [defendant] had actual knowledge that his statement . . . was either false or misleading.").

¹⁴ For a more complete discussion of plaintiffs' failure to adequately plead actual knowledge, see infra Part II.A., discussing the Complaint's insufficient allegations of "fraud."

**II. THE SECTION 10(b) CLAIM FAILS FOR THE
INDEPENDENT REASON THAT IT DOES NOT SATISFY THE
RIGOROUS STANDARDS FOR PLEADING FRAUD AND SCIENTER**

To state a claim for securities fraud under Section 10(b), plaintiffs must satisfy the strict pleading requirements of Fed. R. Civ. P. 9(b) and the PSLRA. Specifically, the complaint must specify: "(1) the statements that the plaintiff contends were fraudulent; (2) the identity of the speaker; (3) where and when the statements were made; and (4) why the statements were fraudulent." Fitzer v. Sec. Dynamics Tech., Inc., 119 F. Supp. 2d 12, 18 (D. Mass. 2000) (dismissing complaint with prejudice for failure to adequately plead securities fraud). Where -- as here -- an allegation concerning the material misstatement is also made upon information and belief, the complaint must "state with particularity all facts on which that belief is formed."¹⁵ Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999) (quoting 15 U.S.C. § 78u-4(b)(1) (emphasis added)). In addition, the PSLRA demands that plaintiffs plead facts giving rise to a strong inference of fraudulent intent, "[a] mere reasonable inference is insufficient to survive a motion to dismiss." Id. at 196 (emphasis added). The PSLRA provides that if a plaintiff does not meet these pleading requirements -- as is the case here -- then the complaint must be dismissed. 15 U.S.C. § 78u-4(b)(3).

¹⁵ Plaintiffs' statement that its allegations are "based upon investigation made by their attorneys" (Compl. Preamble) is equivalent to pleading on information and belief, and does nothing to satisfy plaintiffs' heightened pleading burden. See Carney, 135 F. Supp. 2d at 247 (holding that allegations based upon investigation of counsel must "state with particularity all facts that form the basis for the belief that fraud has occurred").

A. Dismissal Is Required Because The Complaint's Allegations Do Not State With Particularity Facts Supporting A Claim Of Securities Fraud

To comply with the rigorous pleading requirements of Rule 9(b) and the PSLRA, plaintiffs must put forth the particularized factual basis upon which their "information and belief" allegations of fraudulent conduct are predicated. Fitzer, 119 F. Supp. 2d at 20. Indeed, "[Rule] 9(b) requires that the particular times, dates, places, or other details of the alleged fraudulent involvement of the actors be alleged." Id. (emphasis added). Further, the PSLRA statutory requirements include, among other things, particularized allegations that (i) Defendants knew that the statements were false when made and (ii) substantiate claims of why the statements were fraudulent. See Lirette v. Shiva Corp., 27 F. Supp. 2d 268, 276 (D. Mass. 1998) (dismissing complaint because plaintiffs failed to allege with particularity that any fraudulent conduct occurred); see also Orton 344 F. Supp. 2d at 299 (holding that plaintiffs must set forth "specific facts" that make it "reasonable to believe that the defendant knew a statement was materially false or misleading") (emphasis added).

The Complaint's allegations purporting to demonstrate (i) Defendants' "knowledge" and (ii) the reasons why challenged statements were materially false when made are exclusively based upon vague and confusing assertions allegedly provided by eight so-called "confidential sources."¹⁶ But none of those "confidential sources" purport to provide particularized factual allegations that any Defendant knew that a statement was materially false when made. Indeed, Defendants (either collectively or by name) are only referenced in 7 of the approximately 50 paragraphs attributed to the "confidential sources," and none of those para-

¹⁶ Plaintiffs' "confidential sources" purport to be former sales representatives ("CS Nos. 1-6"), a former "regional manager" ("CS No. 7") and a former "staff accountant" ("CS No. 8"). (Compl. ¶¶ 28-35.)

graphs allege with sufficient particularity that Defendants were aware that a challenged statement was materially false or misleading when made. (See Compl. ¶¶ 66, 71, 74, 83, 85, 89 and 102.)

For example, plaintiffs conclusorily allege that the "confidential sources" "believed . . . the Individual Defendants [were] fully aware of [] improper guidance" and "Defendants [] participated in weekly regional and national conference calls with the sales staff." (Id. ¶¶ 66, 102.)

Such non-particularized allegations are insufficient to satisfy the pleading requirements of Rule 9(b) and the PSLRA.

In addition to the Complaint's dispositive failure to adequately plead knowledge of falsity, plaintiffs' generalized factual allegations also do not provide support for why the statements were false or misleading. Indeed, the generic descriptions of events offered by the "confidential sources" do not even support claims of securities fraud. Rather, those allegations are merely complaints of non-actionable mismanagement:

- "the pricing structure for Plenaxis was significantly flawed" (Compl. ¶ 53) -- *this is a mismanagement allegation made with hindsight; no facts suggest that Defendants knew that they had a flawed pricing structure at the time they utilized such structure in the marketplace and provided revenue guidance based on that structure;*
- "Praecis management mistakenly used the combined price of Lupron and Casodex" (id. ¶ 56) -- *where is the allegation that Defendants knew of this mistake when it was made? Of course it is not in the Complaint; it would be absurd to think that Defendants would use a pricing structure that they knew would not work;*
- "Praecis management would attack the qualifications of the sales representatives [and] threaten to fire the sales representatives" (id. ¶ 71) -- *this allegation is simply one of mismanagement, and has nothing to do with allegations of "fraud;"*
- "Management told CS No.5 that his or her market for Plenaxis 'failed' because he or she refused to identify patients" (id. ¶ 72) and "CS No. 5 was troubled by Management's lack of professionalism, intimidation tactics, and the 'Jeckle [sic]

and Hyde' work environment" (*id.* ¶ 73) -- *again, such allegations may support a claim for mismanagement, but not for securities fraud;*

- "Praecis engaged in 'management by intimidation'" and, as a result, "staff morale was extremely low" (*id.* ¶ 91) -- *at best, this is a dispute about poor managerial style, not securities fraud.*

Allegations of poor management are insufficient as a matter of law. *See, e.g., Carney*, 135 F. Supp. 2d at 252 ("[t]here is no liability for securities fraud . . . if what is complained of is poor management"); *see also Van Ormer v. Aspen Tech., Inc.*, 145 F. Supp. 2d 101, 105 (D. Mass. 2000) (dismissing complaint and holding that complaint's allegation "amounts to nothing more than complaints of poor management, not securities fraud").

1. Plaintiffs' Allegations Are Insufficient To Demonstrate That The November 2003 Statements Were Knowingly False When Made

Plaintiffs allege that five statements made in November 2003 were materially false and misleading, but do not support those allegations with particularized facts demonstrating the purported fraudulent nature of those statements. (*See* Compl. ¶¶ 105-109, App. Exs. 1-3.) With the possible exceptions of "CS No. 7" and "CS No. 8," none of the "confidential sources" that plaintiffs cite as support for their allegations were even Praecis' employees during November 2003!¹⁷ (Compl. ¶¶ 28-33.) As to "CS No. 7" and "CS No. 8," the Complaint does not allege a single contemporaneous fact by either of those unidentified sources that Defendants knew that any November 2003 statement was materially false when made.¹⁸

¹⁷ The Complaint describes "CS No. 7" as being employed "from late 2003 until late 2004," and "CS No. 8" "from late 2003 until spring 2004." (Compl. ¶¶ 34-35.)

¹⁸ "CS No. 8" is only referenced once in the Complaint, and only then for the conclusory assertion that "orders [of Plenaxis] from distributors were infrequent -- only a few each week." (Compl. ¶ 70.) Notably, the Complaint does not specify as to when this occurred or for how long.

The only paragraph that even purports to allege facts attributable to a "confidential source" concerning the November 2003 statements is wholly conclusory, and does not even purport to ascribe knowledge to any Defendant: "CS No.7 had seen Defendant Gefters' [November 26, 2003] CNBC interview, and during this interview, stated that Plenaxis would be a tough sell and that at best, Plenaxis had a developed market potential of \$10 to \$20 million per year." (*Id.* ¶ 47.) The Complaint does not say to whom "CS No. 7" purportedly made this statement or what "CS No.7's" quip was based upon. That an anonymous person, while watching a televised interview, made an off-the-cuff remark to another anonymous person or persons expressing disagreement with a statement made in the televised interview regarding possible future market potential of a new drug long before the drug even began to be sold, hardly constitutes particularized facts supporting an allegation either that the statement in the televised interview was false or that the person making the statement knew it was false.

Rather than pleading particularized facts demonstrating Defendants' purported "knowledge" -- which plaintiffs cannot do -- the Complaint impermissibly repeats conclusory allegations from the "confidential sources" that Defendants *must have known* that Plenaxis® "was a 'failed drug' from the beginning." (*Id.* ¶ 100.) With the benefit of 20-20 hindsight, the "confidential sources" conclusorily allege that Defendants *must have known* that the November 2003 statements (*i.e.*, statements made before the drug was even sold) were false when made because:

- "urologists expected to see no more than three patients a year that would need Plenaxis" (*id.* ¶ 47);
- "it was well known within the pharmaceutical industry that a black box warning label causes significant sales difficulties" (*id.* ¶ 48);¹⁹
- competition from another drug would further weaken Plenaxis® sales, particularly since that drug did not have a "black box" warning on its label (*id.* ¶¶ 48-52); and
- Plenaxis'® pricing structure and the FDA imposed PLUS Program would decrease doctors' profits, making it unlikely physicians would even prescribe the drug (*id.* ¶¶ 53-59).

But those "allegations" are nothing more than impermissible "fraud by hindsight," and do not support a claim of fraud. *See, e.g., Van Ormer*, 145 F. Supp. 2d at 105 (holding that "[a]llegations supported only by unidentified 'sales managers' who got their information from unspecified sources fall woefully short of meeting particularity requirements.").

**2. Plaintiffs Fail To Plead Particularized Facts
Sufficient To Support Their Conclusory Assertions
That The January 2004 Statements Were Fraudulent**

Plaintiffs' allegations that three statements made in a January 30, 2004 press release were materially false and misleading are likewise unsupported by particularized factual allegations. (Compl. ¶¶ 112-114, App. Ex. 4.) Plaintiffs contend that those statements were false when made because (i) during unidentified "training sessions . . . it became clear" that Plenaxis® could only be sold through "unethical and potentially illegal sales tactics;" and (ii) "under no conditions" could the internal sales goals meet forecasts. (*Id.* ¶ 115.) These conclusory

¹⁹ This allegation is silly: it is a matter of public knowledge that, for example, Remicade (manufactured by Johnson & Johnson for treatment of Crohn's Disease, among other things) carries a black box warning label yet nevertheless produced \$1.8 billion in sales in 2004. *See* http://www.rxlist.com/top200_sales_2004.htm. The Complaint fails to allege any facts showing that Defendants *knew* "from the beginning" how much the black box warning would effect sales.

assertions are not supported by particularized factual allegations demonstrating knowledge or how these allegations (even if true) support a claim of securities fraud.

Plaintiffs' allegations concerning the unidentified "training sessions" are non-particularized, and insufficient to explain how Defendants' January 2004 statements were false or misleading. (See id. ¶¶ 62-67.) First, the Complaint fails to identify when these sales training sessions purportedly occurred. Moreover, there is not a single allegation that any of the Defendants attended (or knew of) these "training sessions." To the contrary, the "confidential sources" allege that Jeff Sherman ("Sherman") (a non-defendant) "would discuss the Plenaxis market and describe aggressive sales techniques." (Id. ¶ 64.) Then, in a failed attempt to link Defendants to the information allegedly portrayed during the unidentified "training sessions," "CS No. 5" contends that he or she "believed . . . the Individual Defendants [were] fully aware of Sherman's improper guidance" because Sherman "worked closely with [unidentified] Praecis management," and because Marc Garnick (Praecis' Chief Medical Officer) "was present when Sherman directed sales representatives to act improperly." (Id. ¶ 66 (emphasis added).) Anonymous speculation is insufficient to meet Rule 9(b)'s strict pleading requirements.

Plaintiffs' allegations concerning internal sales goals fare no better. (Id. ¶¶ 67-68.) Plaintiffs allege that Sherman told "CS No. 1" that "each sales representative was expected to acquire ten patients each between February 2004 and June 2004," and by plaintiffs' calculation, that goal would not allow Praecis to meet its 2004 sales forecast of \$10-20 million.²⁰ (Id.) Once

²⁰ Oddly, plaintiffs allege that "CS No. 7" agreed with those projections: "Plenaxis had a developed market potential of \$10 to \$20 million per year." (Compl. ¶ 47.)

again, plaintiffs do not allege that this was a goal established by Defendants, or that Defendants even knew of this purported goal. That failure is dispositive.²¹

**3. Plaintiffs Fail To Plead Particularized Facts
Sufficient To Support Their Conclusory Assertions
That The March And April 2004 Statements Were Fraudulent**

Plaintiffs' challenge to three statements made in March and April 2004 as being materially false and misleading similarly lack adequate factual allegations to support a claim of fraud and, consequently, fail as a matter of law. (See Compl. ¶¶ 118-121; App. Exs. 5-7.)

Plaintiffs' conclusory allegation that Plenaxis® "was a dismal failure" at launch is not supported by any particularized (or contemporaneous) factual allegations whatsoever. (Compl. ¶ 69.) "CS Nos. 2, 3 and 8" offer only generalized, post-launch allegations that "urologists did not want to buy Plenaxis," "physicians complained" about Plenaxis® and "orders from distributors were infrequent -- only a few each week [and] . . . only a few vials in each order." (Id. ¶¶ 69-70 (emphasis added).) Once again, plaintiffs fail to provide the necessary factual particularization as to which physicians complained, what did they say, who did they complain to, how often did these complaints occur, what is a "few [orders] each week" and what is a "few vials?" Also absent from the Complaint is even a single allegation that Defendants

²¹ Additionally, plaintiffs engage in "fuzzy math" to support their \$1.68 million calculation. (Compl. ¶ 68.) Using plaintiffs' numbers, but calculating gross sales for the entire year (not just through June 2004 as plaintiffs do) from just those 400 patients allegedly targeted to be acquired over the five months from February 2004 through June 2004, the alleged 10 patient per sales representative goal would generate 13 vials per patient, or a total of 5,200 vials, for gross sales of \$3.64 million. Plaintiffs fail to explain how, when properly calculated, that goal would not allow Praecis to meet its sales forecast, particularly since it is reasonable to assume that product sales would increase after several months on the market. Indeed, Plenaxis® sales did in fact increase over the course of 2004, from \$400,000 in the first quarter, to \$645,000 in the second quarter, to \$1,032,000 in the third quarter. (See App. Exs. 6, 9 and 11 respectively).

were aware of these purported "problems," when and how they became aware and what they were told.

Plaintiffs' allegations of "management by intimidation," failed pricing strategies and low sales force morale similarly fail. (Compl. ¶¶ 71-78, 91-95.) Put simply, allegations of poor management and disagreements with business decisions are not securities fraud. Van Ormer, 145 F. Supp. 2d at 105 (allegation that products were plagued with problems because they were released too early "amounts to nothing more than complaints of poor management, not securities fraud"). See also Fitzer, 119 F. Supp. 2d at 31 ("allegations of disruption and dissension in the sales force . . . and inexperienced and poorly-trained sales and service personnel" are allegations of poor management and "are not actionable under the securities laws.").

**4. Plaintiffs Fail To Plead Particularized Facts
Sufficient To Support Their Conclusory Assertions
That The May Through October 2004 Statements Were Fraudulent**

Plaintiffs impermissibly offer the same type of non-specific allegations of fraud to explain why statements made in May 2004 through October 2004 were materially false and misleading.²² (Id. ¶¶ 125, 133.)

In purported support of the allegation that Defendants were attempting to sell Plenaxis off-label with a new "focused message," plaintiffs rely on generalized assertions from the "confidential sources" that they "were told in early June of 2004 to 'overstate the indications and understate the allergic reactions.'" (Id. ¶ 81.) But the "confidential sources" do not state who said that, who it was said to or in what context.

²² See Compl. ¶¶ 124, 126, 128, 131-132; see also App. Exs. 8, 9, 11.

Similarly deficient are allegations of purported events at a sales meeting in June 21-23, 2004. (*Id.* ¶¶ 83-88.) The "confidential sources" are careful not to ascribe any purported wrongful conduct to any Defendant. Indeed, the "confidential sources" only allege that they "were asked to participate in role-playing exercises" and "were directed to use non-niche phrases." (*Id.* ¶ 88.) So what? These allegations hardly constitute particularized facts supporting even an inference of the wrongdoing being alleged by plaintiffs, let alone a claim for securities fraud.

Even if the Complaint did allege with the requisite specificity that Defendants were promoting off-label indications -- and it does not -- plaintiffs fail to explain how those alleged facts support the asserted claim of securities fraud. Indeed, the promotion of off-label indications simply does not support allegations that any of Defendants' statements in May 2004 through October 2004 were false when made. See *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 401-02 (6th Cir. 1997) (affirming dismissal of complaint and holding that allegations of off-label sales did not render false and misleading public statements concerning the high demand for products and increased sales).

B. Plaintiffs' Catch-All Allegations Of Scienter Are Conclusory And, Accordingly, Do Not Raise The Requisite Strong Inference Of Scienter

The Complaint also should be dismissed for the independent reason that plaintiffs fail to "state with particularity facts giving rise to a strong inference that [Defendants] acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (emphasis added). To adequately plead scienter, the Complaint must set forth particularized facts that "defendants acted with either knowing, intentional falsity or reckless disregard for the truthfulness of the statements." *In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 189, 214 (1st Cir. 2005) (affirming dismissal of

securities claims brought against external auditor on the grounds that scienter is not adequately plead by "conclusory assertion[s] that the defendant knew the true facts, or knew that the challenged statement[s] [were] false"). Dismissal is mandated unless plaintiffs' characterization of facts "support[s] a highly likely inference that the defendant acted with the required state of mind." Id. (emphasis added) (quotation omitted).

1. Conclusory Allegations That Defendants Had Access To Unspecified Information Due To Their Positions Are Insufficient To Raise A Strong Inference Of Scienter

Having failed to plead actual knowledge of falsity, plaintiffs conclusorily assert that Defendants *must have known* that Plenaxis® "was a 'failed drug' from the beginning" due to their positions within the company, conversations and connections that they must have had with others and access they had to reports generated by Praecis' computerized sales system. (Id. ¶¶ 100-102, 140-142.) Courts routinely reject such boilerplate allegations that Defendants *must have known* about purported fraudulent conduct because he or she had access to internal company information. Maldonado v. Dominguez, 137 F.3d 1, 9-10 (1st Cir. 1998) (rejecting allegations that defendants must have been aware of facts by virtue of their positions); Orton, 344 F. Supp. 2d at 306 ("a vague assertion that a defendant must have known about the fraud by virtue of his position of authority [does not] suffice to prove a strong inference of scienter"); Carney, 135 F. Supp. 2d at 255 ("status" and "general allusions to unspecified corporate information" insufficient to "meet[] the rigorous requirements for pleading scienter").

Plaintiffs' non-specific allegations concerning the SPIDER computer system also are inadequate to raise a strong inference of scienter. (Compl. ¶¶ 101-103.) Plaintiffs speculate that "Defendants could use SPIDER" and "it was possible to graph sales performance," but that is

nothing more than the conclusory (and inadequate) allegation that because of their positions, Defendants must have had access to data from SPIDER. (*Id.* ¶ 101.) Moreover, absent from the Complaint are allegations of when SPIDER included this allegedly poor data, what specific report, if any, are plaintiffs referring to and how does that information support the conclusory allegation that Plenaxis® "was a 'failed drug.'" These details are particularly crucial here because on May 24, 2004 -- more than 6 months before the purported class period ends -- Praecis informed investors that Plenaxis® sales had been "slower than forecasted" and, as a result, could not "confirm its previously issued sales range forecast for 2004." (App. Ex. 8 at 2.) Plaintiffs' non-specific allegations are too vague to raise an inference of scienter -- let alone the requisite strong one.

Plaintiffs' allegations concerning unidentified "conference calls" also miss the mark. (*Id.* ¶ 102.) Plaintiffs allege that "CS No.1" submitted written evaluations to "management," but do not say who in "management" those were submitted to, when they were submitted or what they purportedly contained. "CS No. 2's" allegation that he or she "spoke to . . . defendants [] Gefter and [] McLaughlin" similarly fail in the absence of such details as when he or she spoke to Defendants or what was said.²³ (*Id.*)

2. Mere Allegations Of Stock Sales By A Single Defendant Fail To Raise A Strong Inference Of Scienter

Plaintiffs' allegation that defendant Gefter sold 600,000 shares of Praecis' securities during the putative thirteen-month class period is unavailing. (*Id.* ¶ 143.) Indeed, plaintiffs fail to allege much of anything aside from the number of shares sold, and ignore

²³ Plaintiffs also allege that "CS No. 7 stated by the end of 2004, sales were closer to \$1 million." (Compl. ¶ 98.) That allegation is simply false. Plenaxis® sales totaled \$2,088,000 through September 30, 2004 alone. (See App. Ex. 11 at 2.)

entirely any facts as to the pattern or timing of those sales.²⁴ Courts uniformly hold that mere allegations of stock sales by a defendant, without more, do not (and cannot) give rise to a strong inference of scienter. Greebel, 194 F.3d at 198 (holding that stock sales do not raise a strong inference of scienter without allegations that the trading was "unusual, well beyond the normal patterns of trading"); Carney, 135 F. Supp. 2d at 256 (allegations of stock sales insufficient to raise strong inference of scienter where "[n]othing . . . is said about whether these sales were inconsistent with any pattern established by these defendants in either amount or to timing").

III. THE SECTION 10(b) CLAIM FAILS FOR THE ADDITIONAL REASON THAT PLAINTIFFS DO NOT ADEQUATELY PLEAD LOSS CAUSATION

In addition to satisfying the rigorous pleading requirements of Rule 9(b) and the PSLRA, to state a claim under Section 10(b) plaintiffs must also plead "loss causation" -- that is, "a causal connection between the material misrepresentation and the loss." Dura, 125 S. Ct. 1627 at 1631 (affirming dismissal). A plaintiff does not sufficiently plead loss causation where -- as here -- the complaint's allegations are limited to conclusory assertions that plaintiff purchased stock at an inflated price. Id. Rather, a plaintiff must allege facts that support an inference that his loss was caused by the information misstated or concealed by the defendant. In other words, plaintiffs must allege "that [their] loss [was] caused by the materialization of [a] concealed risk." Lentell v. Merrill Lynch & Co. Inc., 396 F.3d 161, 173 (2d Cir. 2005).

In Lentell, plaintiffs brought suit alleging securities violations predicated upon allegations that defendants issued false "buy" and "accumulate" recommendations for certain

²⁴ Based on publicly-filed documents, defendant Geffer sold 300,000 shares on December 2, 2003 (just one week after Plenaxis® received FDA approval), and the remaining 300,000 shares on February 3 and 4, 2004 (prior to the full launch of Plenaxis®). (See SEC Forms 4 dated December 3, 2003 and February 5, 2004, App. Exs. 15 and 16.)

internet companies (and thereby inflating the price of securities for those companies) in hope to secure investment banking business. Id. at 165-66. As to loss causation, plaintiffs alleged that they purchased stock at "artificially inflated prices" and, as a result "were damaged thereby." Id. at 175. In affirming dismissal, the Court found no loss causation in allegedly false investment recommendations because defendants disclosed that the companies were "volatile investments, and therefore subject to sudden and substantial devaluation risk." Id. at 176. Accordingly, where a previously disclosed risk materializes, in order to plead loss causation plaintiffs must allege facts sufficient to support an inference that it was the alleged fraud, rather than the realization of the disclosed risk, that caused their loss:

where [] substantial indicia of the risk that materialized are unambiguously apparent on the face of the disclosures alleged to conceal the very same risk, a plaintiff must allege (i) facts sufficient to support an inference that it was defendant's fraud -- rather than other salient factors -- that proximately caused plaintiff's loss; or (ii) facts sufficient to apportion the losses between the disclosed and concealed portions of the risk that ultimately destroyed an investment. Id. at 177.

The Complaint here does not adequately plead loss causation. Plaintiffs' sole loss causation allegations are that they purchased Praecis stock at artificially inflated prices, and the stock price declined after Praecis' December 6, 2004 disclosure. (Compl. ¶¶ 11, 137-39.) But nowhere do plaintiffs even attempt to provide the requisite "causal connection" between the decline in stock price and Defendants' purported fraudulent conduct. Dura, 125 S. Ct. at 1634. Nor could they. As the following chart demonstrates, plaintiffs cannot establish that Defendants' alleged misstatements caused their "loss" because Praecis' December 6, 2004 press release informed the market that a known, prior disclosed risk had materialized:

<u>December 6, 2004 Disclosure</u>	<u>Previously Disclosed Risks</u>
<p>"The Company has found that educating physicians about the Plenaxis(R) User Safety (PLUS) Program and the appropriate patient population for Plenaxis(R) has markedly increased the sales cycle and requires a very focused sales message and sales call." (12/6/04, App. Ex. 14 at 1.)</p>	<p>"Many factors may affect the market acceptance and commercial success of Plenaxis or any of our other potential products, including:</p> <ul style="list-style-type: none"> • the scope of the patient population and the indications for which Plenaxis . . . [is] approved; • the terms of any risk management and/or controlled or managed distribution program required by the FDA in connection with the approval of Plenaxis" <p>(Form 10-Q for the period ending September 30, 2003, App. Ex. 12 at 16.)²⁵</p>
<p>"In addition, physicians' concerns over obtaining reimbursement coverage for Plenaxis(R) during the initial launch phase have been compounded this quarter by increasing physician uncertainty regarding the impact of changing pharmaceutical reimbursement for 2005 as a result of recent Medicare reform." (<u>Id.</u>)</p>	<p>"Many factors may affect the market acceptance and commercial success of Plenaxis or any of our other potential products, including:</p> <p>...</p> <ul style="list-style-type: none"> • the rate at which Plenaxis . . . [is] reimbursed by third-party payors, in particular Medicare <p>...</p> <ul style="list-style-type: none"> • the cost effectiveness of Plenaxis . . . and the availability of insurance or other third-party reimbursement, in particular, Medicare, for patients using our products" (<u>Id.</u>)²⁶
<p>". . . the Company has decided to remove its previous short and long term sales and earnings guidance, and does not currently anticipate providing further guidance until a consistent trend for Plenaxis(R) sales emerges." (<u>Id.</u> at 2.)</p>	<p>". . . the uptake of [Plenaxis] by prescribers during the initial sixteen weeks has been somewhat slower than forecasted. Accordingly, the Company is not in a position at this time to confirm its previously issued sales range forecast for 2004." (5/24/04, App. Ex. 8 at 2.)</p>

²⁵ In addition to this pre-class period disclosure, Praecis made similar repeated disclosures in its public filings throughout the purported class period. (See App. Ex. 7 at 16-17 (Form 10-Q for period ending 3/31/04); App. Ex. 10 at 19 (Form 10-Q for period ending 6/30/04); App. Ex. 13 at 31-32 (Form 10-K for period ending 12/31/03); App. Ex. 17 at 19-20 (Form 10-Q for period ending 9/30/04).)

²⁶ Id.

Thus, because the risk that ultimately materialized was disclosed, plaintiffs cannot plead loss causation.

IV. PLAINTIFFS HAVE FAILED TO STATE A SECTION 20(a) CLAIM

Without a viable primary violation of the Exchange Act, there is no basis to maintain a claim under Section 20(a). See Parametric Tech., 300 F. Supp. 2d at 224 (holding that "where there is no liability under Section 10(b), it must follow that there is none under Section 20(a), regardless of an individual defendant's position or influence within a company").

Furthermore, the Section 20(a) claim fails because plaintiffs have not adequately pled "culpable participation" on the part of any of the Individual Defendants. Indeed, the Complaint simply contains no allegations sufficient to demonstrate that the Individual Defendants knowingly, actively or even meaningfully participated in making statements with actual knowledge of their falsity. See SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996) cert. denied, 522 U.S. 812 (1997).²⁷

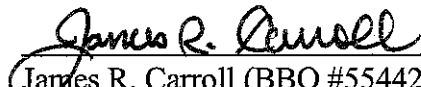
CONCLUSION

For all of the foregoing reasons, Defendants' Motion to Dismiss should be granted in its entirety and the Complaint dismissed with prejudice and without leave to further amend.

²⁷ The First Circuit has declined to rule on whether culpable participation is an element of a Section 20(a) claim. See Stone & Webster, 414 F.3d at 196 n.6.

Dated: September 12, 2005
Boston, Massachusetts

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Michael S. Hines, hereby certify that on September 12, 2005, I caused a true copy of the foregoing Memorandum Of Law In Support Of Defendants' Motion To Dismiss The Consolidated Amended Complaint to be served by hand upon counsel for plaintiffs, David Pastor, Esq., Gilman and Pastor, LLP, 60 State Street, 37th Floor, Boston, Massachusetts, 02109; and by overnight mail, postage prepaid, upon Jacqueline Sailer, Esq. and Lawrence D. McCabe, Esq., Murray, Frank & Sailer LLP, 275 Madison Avenue, Suite 801, New York, New York 10016 and Peter Binkow, Esq., 1801 Avenue of the Stars, Suite 311, Los Angeles, California 90067.

Dated: September 12, 2005



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